

Treatment Intervention Advisory Committee Review and Determination

Date: June 29, 2018

To: Wisconsin Department of Health Services

From: Wisconsin Department of Health Services Treatment Intervention Advisory Committee:

Lana Collet-Klingenberg, Ph.D. (chairperson) *LCK*

RE: Determination of P.L.A.Y. Project as a proven and effective treatment for children and adults

- This is an initial review
- This is a re-review. Previously reviewed (rated) on August 17, 2012 (4), July 26, 2013 (4), July 25, 2014 (4) and January 20, 2015 (4), January 29, 2016 (5).
- No new research located; determination from , stands (details below)
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Section One: Overview and Determination

Please find below a statement of our [determination](#) as to whether or not the committee views P.L.A.Y. Project as a proven and effective treatment. In subsequent sections you will find documentation of our review process including a [description](#) of the proposed treatment, a [synopsis](#) of review findings, the [treatment review evidence checklist](#), and a listing of the [literature](#) considered. In reviewing treatments presented to us by the Department of Health Services, we implement a review process that carefully and fully considers all available information regarding a proposed treatment. Our determination is limited to a statement regarding how established a treatment is with regards to quality research. The committee does not make decisions regarding funding.

Description of proposed treatment

From the PLAY Project website (www.playproject.org/about): the "PLAY Project is an evidenced-based parent-mediated autism intervention model that can be learned and delivered by experts in child development. PLAY Project offers a certification training and supervision combination that prepares trainees to deliver the intervention with fidelity (in accordance with the research)... Richard Solomon, M.D., a developmental and behavioral pediatrician, developed this program in response to the lack of availability of intensive early intervention services for children with ASD. He designed the PLAY Project early intervention program as a cost effective, practical approach. PLAY has been implemented as a primary intervention for ASD in early intervention settings and often supplements existing services (e.g. special education, language and occupational therapies, and/or ABA/behavioral interventions)... The principles, methods and techniques of the PLAY Project emphasize the child's readiness or following the child's lead as a means for improving social impairment, a core deficit of autism spectrum disorder. Professionals coach parents to build a joyous, engaged relationship with their child with autism spectrum disorder... The PLAY Project's mission is to train a global network of pediatric professionals to deliver an evidence-based, low-cost, intensive developmental intervention to families of young children with autism spectrum disorders."

The intervention is based on Greenspan's Functional Developmental Levels and emphasizes quality of social reciprocity, specifically length of joint engagement, initiations, and reciprocal social exchanges. Parents are trained by certified consultants, and parents are asked to play with their child and use the techniques taught for at least 2 hours per day.

Synopsis of current review (June 2018)

Committee members completing current review of research base: Amy Van Hecke and Tia Schultz

Please refer to the reference list ([Section Four](#)) which details the reviewed research.

One additional, peer-reviewed study has appeared since the last review in 2016, Mahoney and Solomon, 2016. This study was a re-analysis of the Solomon et al., 2014, study data, investigating mediating effects on treatment outcomes. Although the study found interesting mediational effects, it is concluded that, overall, it does not change the overall level of this treatment, as the study was again conducted by the developers of the treatment. To be counted as "high-quality," there must be at least one peer-reviewed, scholarly study authored by someone other than the developer of the treatment. Further, the PLAY treatment has yet to attain recognition by authoritative bodies as an Evidence-Based Practice for ASD.

Committee's Determination: After reviewing the research and applying the criteria from the [Treatment Review Evidence Checklist](#), it is the decision of the committee that P.L.A.Y. Project retain an efficacy rating of Level 4 (Insufficient Evidence).

Review history

(January 2016)

No additional data have appeared since the last review in 2015.

(January 2015)

Since the last review in July 2014, one additional peer-reviewed, published study was found and reviewed (Solomon et al., 2014). Additionally, there is one other experimental, group study on the PLAY Project (Solomon et al., 2007). Both studies were done by the PLAY Project developers. The 2007 study did not include any control group, and thus it is unclear whether changes attributed to the PLAY Project were actually due to the treatment or were due to general development. The 2014 study, in contrast, was a very high quality randomized controlled study done over multiple sites, with a large number of children, with high fidelity and reliability of measures. The 2014 study showed significant improvements in both parent and child social behaviors, and in parent depression, vs. a community control group. Additionally, children in the PLAY Project group were 2.39 times more likely to move up an ADOS diagnostic category, over one year, than the control group, a significant difference. It is particularly important that the 2014 study showed gains in social-emotional domains, which are areas that are exceedingly relevant for very young children. This 2014 study, overall, is an important contribution in regards to the PLAY Project as a complementary treatment for ASD.

However, the standards given here require that, to be classified as a Level 3 or higher treatment, the study must be high quality: defined as being conducted by someone other than the developer of the

treatment, and as being recognized by other authoritative bodies as being an effective treatment for ASD. The peer-reviewed PLAY Project studies (2007 and 2014) were both done by the PLAY Project developer. Also, although the National Professional Development Center lists Parent-Implemented Intervention (PII) as an Evidence-Based Practice, the PLAY Project is not listed as one of the packages providing evidence for PII. The PLAY Project is also not listed by the National Standards Project as an EBP, or on the American Speech and Hearing Association (ASHA) ASD treatments site as an EBP. Therefore, the PLAY Project has yet to attain recognition by other authoritative bodies as an Evidence-Based Practice for ASD.

In sum, it is the decision of the committee that the PLAY Project has insufficient evidence of effectiveness, and should remain as considered: Level 4- Insufficient Evidence (Experimental Treatment).

(July 2014)

The committee's conclusions regarding PLAY include:

- There is still only one 2007 experimental, group study on PLAY, despite a large, NIMH funded study having been completed within the last two years.
- The one 2007 study available was done by the PLAY developers and did not include any control group.
- It is unclear whether changes attributed to PLAY were actually due to the treatment or were due to general development.

In sum, it is the decision of the committee that PLAY has insufficient evidence of effectiveness, and should remain as considered- Level 4 – Insufficient Evidence (Experimental Treatment).

(July 2013)

Two additional chapters, and no additional research studies were found for this re-review. It is the committee's decision that the P.L.A.Y. Project program has insufficient evidence at this time to be considered a proven and effective treatment.

(August 2012)

The committee maintains the following conclusions regarding the P.L.A.Y. Project:

- There are insufficient data available to draw meaningful conclusions about its efficacy for individuals with ASD and/or other developmental disabilities.
- One published article was available for review that included data collection and analysis regarding the specific treatment package for the P.L.A.Y Project. This was a pilot study that included the developer directly in the research project. Independent investigations and/or replication studies were not found in the published literature.
- A majority of the available material reviewed consists of reference lists regarding the evidence basis of developmental, play based therapies generally, as well as published research that addresses treatments that follow a similar theoretical foundation.
- The P.L.A.Y Project is not currently cited in major summary reviews of evidenced –based practices for Autism (i.e., National Standards Report, Association for Science in Autism Treatment (ASAT) review of treatments)

- Research funded by the National Institutes of Mental Health is currently in process, however no information or data is available related to efficacy or outcomes at this time.

In sum, given the general lack of empirical support for the P.L.A.Y. Project program, as well as research directly related to the P.L.A.Y. Project program as a comprehensive treatment package, it is our decision that the P.L.A.Y. Project program has insufficient evidence at this time to be considered a proven and effective treatment. While we do not believe it is a harmful practice, at this time, this committee considers it an experimental practice.

Section Two: Rationale for Focus on Research Specific to Comprehensive Treatment Packages (CTP) or Models

In the professional literature, there are two classifications of interventions for individuals with Autism Spectrum Disorder (National Research Council, 2001; Odom et al., 2003; Rogers & Vismara, 2008):

- (a) **Focused intervention techniques** are individual practices or strategies (such as positive reinforcement) designed to produce a specific behavioral or developmental outcome, and
- (b) **Comprehensive treatment models** are “packages” or programs that consist of a set of practices or multiple techniques designed to achieve a broader learning or developmental impact.

To determine whether a treatment package is proven and effective, the Treatment Intervention Advisory Committee (TIAC) will adopt the following perspective as recommended by Odom et al. (2010):

The individual, focused intervention techniques that make up a comprehensive treatment model may be evidence-based. The research supporting the effectiveness of separate, individual components, however, does *not* constitute an evaluation of the comprehensive treatment model or “package.” The TIAC will consider and review only research that has evaluated the efficacy of implementing the comprehensive treatment *as a package*. Such packages are most often identifiable in the literature by a consistently used name or label.

National Research Council. (2001). *Educating children with autism*. Washington, DC: National Academy Press.

Odom, S. L., Brown, W. H., Frey, T., Karusu, N., Smith-Carter, L., & Strain, P. (2003) Evidence-based practices for young children with autism: Evidence from single-subject research design. *Focus on Autism and Other Developmental Disabilities, 18*, 176-181.

Odom, S. L., Boyd, B. A., Hall, L. J., & Hume, K. (2010). Evaluation of comprehensive treatment models for individuals with Autism Spectrum Disorders. *Journal of Autism and Developmental Disorders, 40*, 425-436.

Rogers, S., & Vismara, L. (2008). Evidence-based comprehensive treatments for early autism. *Journal of Clinical Child and Adolescent Psychology, 37*, 8-38.

Section Three: TIAC Treatment Review Evidence Checklist

Name of Treatment: P.L.A.Y. Project

Level 1- Well Established or Strong Evidence (DHS 107 - Proven & Effective Treatment)

- Other authoritative bodies that have conducted extensive literature reviews of related treatments (e.g., National Standards Project, National Professional Development Center) have approved of or rated the treatment package as having a strong evidence base; authorities are in agreement about the level of evidence.
- There exist ample high quality studies that demonstrate experimental control and favorable outcomes of treatment package.
 - Minimum of two group studies or five single subject studies or a combination of the two.
 - Studies were conducted across at least two independent research groups.
 - Studies were published in peer reviewed journals.
- There is a published procedures manual for the treatment, or treatment implementation is clearly defined (i.e., replicable) within the studies.
- Participants (i.e., N) are clearly identified as individuals with autism spectrum disorders or developmental disabilities.

Notes: At this level, include ages of participants and disabilities identified in body of research

Level 2 – Established or Moderate Evidence (DHS 107 - Proven & Effective Treatment)

- Other authoritative bodies that have conducted extensive literature reviews of related treatments (e.g., National Standards Project, NPDC) have approved of or rated the treatment package as having at least a minimal evidence base; authorities may not be in agreement about the level of evidence.
- There exist at least two high quality studies that demonstrate experimental control and favorable outcomes of treatment package.
 - Minimum of one group study or two single subject studies or a combination of the two.
 - Studies were conducted by someone other than the creator/provider of the treatment.
 - Studies were published in peer reviewed journals.
- Participants (i.e., N) are clearly identified as individuals with autism spectrum disorders or developmental disabilities.

Notes: at this level, include ages of participants and disabilities identified in body of research

Level 3 – Emerging Evidence (DHS 107 – Promising as a Proven & Effective Treatment)

- Other authoritative bodies that have conducted extensive literature reviews of related treatments (e.g., National Standards Project, NPDC) have recognized the treatment package as having an emerging evidence base; authorities may not be in agreement about the level of evidence.
- There exists at least one high quality study that demonstrates experimental control and favorable outcomes of treatment package.
 - May be one group study or single subject study.
 - Study was conducted by someone other than the creator/provider of the treatment.
 - Study was published in peer reviewed journal.
- Participants (i.e., N) are clearly identified as individuals with autism spectrum disorders or developmental disabilities.

Notes: At this level, include ages of participants and disabilities identified in body of research

Level 4 – Insufficient Evidence (Experimental Treatment)

- Other authoritative bodies that have conducted extensive literature reviews of related treatments (e.g., National Standards Project, NPDC) have not recognized the treatment package as having an emerging evidence base; authorities are in agreement about the level of evidence.
- There is not at least one high quality study that demonstrates experimental control and favorable outcomes of treatment package.
 - Study was conducted by the creator/provider of the treatment.
 - Study was not published in a peer reviewed journal.
- Participants (i.e., N) are not clearly identified as individuals with autism spectrum disorders or developmental disabilities.

Notes:

Level 5 – Untested (Experimental Treatment) &/or Potentially Harmful

- Other authoritative bodies that have conducted extensive literature reviews of related treatments (e.g., National Standards Project, NPDC) have not recognized the treatment package as having an emerging evidence base; authorities are in agreement about the level of evidence.
- There are no published studies supporting the proposed treatment package.
- There exists evidence that the treatment package is potentially harmful.**
 - Authoritative bodies have expressed concern regarding safety/outcomes.
 - Professional bodies (i.e., organizations or certifying bodies) have created statements regarding safety/outcomes.

Notes: At this level, please specify if the treatment is reported to be potentially harmful, providing documentation

References Supporting Identification of Evidence Levels:

- Chambless, D.L., Hollon, S.D. (1998). Defining empirically supported therapies. *Journal of Consulting and Clinical Psychology, 66(1)* 7-18.
- Chorpita, B.F. (2003). The frontier of evidence---based practice. In A.E. Kazdin & J.R. Weisz (Eds.). *Evidence-based psychotherapies for children and adolescents* (pp. 42---59). New York: The Guilford Press.
- Odom, S. L., Collet-Klingenberg, L., Rogers, S. J., & Hatton, D. (2010). Evidence-based practices in interventions for children and youth with autism spectrum disorders. *Preventing School Failure, 54(4)*, 275-282.

Section Four: Literature Review

Literature reviewed for current determination:

Mahoney, G., & Solomon, R. (2016). Mechanism of developmental change in the PLAY project home consultation program: Evidence from a randomized, controlled trial. *Journal of Autism and Developmental Disorders*, 46 (5), 1860-1871.

Literature reviewed for previous determinations:

2013-2014 Reviews

In the case of the P.L.A.Y. Project program, there is limited experimental research documenting either its use or its effectiveness. There is to date, one primary data-based resource, which involves a pilot study that included the developer. The materials considered for the initial review included:

Dawson, G., Rogers, S., Munson, J., Smith, M., Winter, J., Greenspan, J., Donaldson, A., & Varley, J (2010). Randomized, controlled trial of an intervention for toddlers with autism: The early start denver model, *Pediatrics*, 125 (1)

The PLAY Project (2011) Scientific Evidence for Intensive Developmental Interventions (IDI). (no date) Unpublished reference list.

The PLAY Project (2011) Randomized controlled trial of the P.L.A.Y. Project intervention model for autism: Abstract (no date), Unpublished grant proposal abstract.

Solomon, R., Necheles, J., Ferch, C., & Bruckman, D. (2007). Pilot study of a treatment program for young children with autism: The P.L.A.Y. project home consultation program, *Autism*, 11(3), 205-224.

Solomon, R. (2008). Play based intervention for very young children with autism: The PLAY project, In *Play therapy for very young kids*. Kelly-Zion, S., Schaefer, C., McCormick, J., & Ohnoqi, A. (eds). Maryland: Jason Aronson

Solomon, R. "The PLAY project: A train-the-trainer model for young children with autism" *Play Based Interventions for Children and Adolescents with Autism Spectrum Disorders*. Eds. Loretta Gallo-Lopez and Larry Rubin (Co-Editors). Routledge Press (2012 in press).

Solomon, R. "Play Therapy for Very Young Children: The PLAY Project" in *Play Therapy for Very Young Children*. Ed. Charles Schaefer. Rowman and Littlefield (2008).

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Solomon, R., Van Egeren, L., Mahoney, G., Quon-Huber, M., & Zimmerman, P. (2014). PLAY Project home consultation intervention program for young children with Autism Spectrum Disorders: A Randomized controlled trial. *J Dev Beh Pediatr*, 35(8): 475-485